Human Rights Regulations
Frequently Asked Questions #4
03/15/02

Section of Regulations	Clarification Requested	Clarification Provided
Definitions **12 VAC 35-115-30**	**Section of the regulation in question:** **12 VAC 35-115-30. Definitions.** **"Consent" means the voluntary and expressed agreement of an individual, or that individual's legally authorized representative if the individual has one. Informed consent is needed to disclose information that identifies an individual receiving services. Informed consent is also needed before a provider may provide treatment to an individual which poses risk of harm greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations, tests, or treatments, or before an individual participates in human research. Informed consent is required for surgery, aversive treatment, electroconvulsive treatment, and use of psychoactive medications…** Clarification requested: What does "psychoactive" mean in this section of the regulations?	The term "psychoactive" as used in the *Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services* refers to any medication that is required by the FDA to have a black box warning on the prescribing information. This would include but not be limited to the following medications: carbamazepine, thioridazine, clozapine, divalproex sodium, droperidol and nefazodone. Any other medication that meets the following standard in the regulations would also require informed consent. … "Informed consent is also needed before a provider may provide treatment to an individual which poses risk of harm greater than that ordinarily encountered in daily life…"

Access to and correction of services records 12 VAC 35-115-90	**<u>Section of the regulation in question:</u>** **12 VAC 35-115-90. Access to and correction of services records.** **A. Each individual has a right to see, read, and get a copy of his own services record. Minors must have their parent or guardian's permission first. If this right is restricted according to law, the individual has a right to let certain other people see his record. Each individual has a right to challenge, correct or explain anything in his record. Whether or not corrections are made as a result, each individual has a right to let anyone who sees his record know that he tried to correct or explain his position and what happened as a result. An individual's legally authorized representative has the same rights as the individual himself has (see § 2.2-3806 of the Code of Virginia).** <u>Clarification requested</u>: If a minor requests access to their record, and the parent refuses, does the child have an appeal process? Where the minor must have "permission" of the parent to access their own record, does this also have to be the custodial parent? Does this have to be written consent or can it be verbal?	The regulations do not provide for an appeal process based on the premise that the minor is limited by parent/guardian's wishes in many circumstances. Permission for minors to access their record must be provided by the guardian of the minor. If there has been a divorce and one parent is the custodial parent, either parent may still give permission, as long as the court order granting custody does not terminate parental rights. The consent to release the record to a minor must be written per **12 VAC 35-115-80 Confidentiality B, 4.**

Confidentiality **12 VAC 35-115-80**	**Section of the regulation in question:** **12 VAC 35-115-80 Confidentiality** **A. Each individual is entitled to have all information that a provider maintains or knows about him remain confidential. Each individual has a right to give his consent before the provider shares information about him or his care unless another law, federal regulation, or these regulations specifically require or permit the provider to disclose certain specific information.** **B. The provider's duties.** **4. If consent to disclosure is required, providers shall get the written consent of the individual or the legally authorized representative, as applicable, before disclosing information. In the case of a minor, the consent of the custodial parent or other person authorized to consent to the minor's treatment under § 54.1-2969 is required, except as provided below:** **a. Section 54.1-2969 E of the Code of Virginia permits a minor to authorize the release of records related to medical or health services for a sexually transmitted disease or family planning but requires parental consent for release of records related to outpatient care, treatment or rehabilitation for mental illness or emotional disturbance.** Clarification requested: What is the definition of Custodial and non custodial parent as it applies to release of information on minors?	If one (or both) parents are granted custody, there will be an order from Juvenile and Domestic Relations Court designating custody.

Confidentiality **12 VAC 35-115-80**	**Section of the regulation in question:** **12 VAC 35-115-80 Confidentiality** **C. Exceptions and conditions to the provider's duties.** **2. Providers may disclose the following information without consent or violation of the individual's confidentiality, but only under the conditions specified in this subdivision and in subdivision 3 of this subsection. Providers should always consult 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records, if applicable, because these federal regulations may prohibit some of the disclosures addressed in this section. See also §32.1-127.1:03 of the Code of Virginia for a list of circumstances under which records may be disclosed without consent.** **5. When providers disclose information, they shall attach a statement that informs the person receiving the information that it must not be disclosed to anyone else unless the individual consents or unless the law allows or requires further disclosure without consent.** Clarification requested: If a record has a consent to release information for billing purposes that is over a year old, would a subsequent release for the purpose of a Medicaid audit be considered without consent?	**A Medicaid audit would not require consent.** The issue however is not the year old consent but rather the purpose of the release of information. An "audit" would be the same as for "billing purposes". **12 VAC 35-115-80. Confidentiality.** **C. Exceptions and conditions to the provider's duties.** **2. Providers may disclose the following information without consent or violation of the individual's confidentiality, but only under the conditions specified in this subdivision and in subdivision 3 of this subsection. Providers should always consult 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records, if applicable, because these federal regulations may prohibit some of the disclosures addressed in this section. See also § 32.1-127.1:03 of the Code of Virginia for a list of circumstances under which records may be disclosed without consent.** **c. Insurance companies and other third party payers: Disclosure may be made to insurance companies and other third party payers according to Chapter 12 (§ 37.1-225 et seq.) of Title 37.1 of the Code of Virginia.** **g. Others authorized or required by the commissioner, CSB or private program director: Providers may disclose information to other persons if authorized or required by the commissioner, CSB or private program director for the following activities:** **(1) Licensing, human rights, certification or accreditation reviews;** **(2) Hearings, reviews, appeals or investigations under these regulations;** **(3) Evaluation of provider performance and individual outcomes (see § 37.1-98.2 of the Code of Virginia);** **(4) Statistical reporting;** **(5) Preauthorization, utilization reviews, financial and related administrative services reviews and**

Participation in decision making. **12 VAC 35-115-70**	**Section of the regulation in question:** **12 VAC 35-115-70. Participation in decision making.** **B. The provider's duties.** **7. If the capacity of an individual to give consent is in doubt, the provider shall make sure that a professional qualified by expertise, training, education, or credentials and not directly involved with the individual conducts an evaluation and makes a determination of the individual's capacity.** **9. When it is determined that an individual lacks the capacity to give consent, the provider shall designate a legally authorized representative. The director shall have the primary responsibility for determining the availability of and designating a legally authorized representative in the following order of priority:** Clarification requested: Are LARs only assigned when the capacity is in doubt? Is there a time limit to assign an LAR? What is the difference between and LAR and a Substitute Decision Maker? Is an LARs appointment time limited?	The appointment of a legally authorized representative (LAR) is done only when an individual has been determined to lack the capacity to give consent. If an individual has been determined to lack the capacity to give consent a LAR must be assigned before treatment can be provided. Emergency treatment can be provided without consent per **12 VAC 35-115-70. Participation in decision making C, 1.** The term Substitute Decision Maker comes from the Health Care Decisions Act (HCDA). A LAR is one type of Substitute Decision Maker. A person becomes a LAR when they have been so designated by the director. LAR appointments are not time limited per se. However the individual's need for a LAR must be reviewed per **12 VAC 35-115-70. Participation in decision making.** **13. Providers shall make sure that an individual's capacity to consent is reviewed at least every six months or as the individual's condition warrants according to sound therapeutic practice to assess the continued need for a surrogate decision-maker. Such reviews, or decisions not to review, shall be documented in the individual's services record and communicated in writing to the surrogate decision-maker. Providers shall also consider an individual's request for review in a timely manner.**

Dignity **12 VAC 35-115-50**	**Section of the regulation in question:** **12 VAC 35-115-50. Dignity.** **D. In services provided in residential settings, each individual has the right to:** **4. Practice a religion and participate in religious services subject to their availability, provided that such services are not dangerous to self or others and do not infringe on the freedom of others.** **E. Exceptions and conditions to the provider's duties.** **2. The provider may prohibit any religious services or practices that present a danger of bodily injury to any individual or interfere with another individual's religious beliefs or practices. Participation in religious services or practices may be reasonably limited by the provider in accordance with other general rules limiting privileges or times or places of activities.** Clarification requested: Do the regulations permit the restriction of religious practice if the harm to the person is psychological?	The regulations clearly state that the prohibition is on religious practices that present a danger of bodily injury… The regulations do not mention psychological harm. Although psychological harm is not bodily harm, they may only participate if the services "are not dangerous to self or others. . ." It is a clinical determination whether the practice is a danger to self by being a psychological danger.

Participation in decision making. **12 VAC 35-115-70**	**Section of the regulation in question:** **12 VAC 35-115-70. Participation in decision making.** **C. Exceptions and conditions to the provider's duties.** **1. Providers, in an emergency, may initiate, administer, or undertake a proposed treatment without the consent of the individual or the individual's legally authorized representative. All emergency treatment shall be documented in the individual's services record within 24 hours.** **a. Providers shall immediately notify the legally authorized representative, as applicable, of the provision of treatment without consent during an emergency.** **b. Providers shall continue emergency treatment without consent beyond 24 hours only following a review of the individual's condition and if a new order is issued by a professional who is authorized by law and the provider to order the treatment.** **c. Providers shall notify the human rights advocate if emergency treatment without consent continues beyond 24 hours.** **d. Providers shall develop and integrate treatment strategies to address and prevent future such emergencies to the extent possible, into the individual's services plan, following the provision of emergency treatment without consent.** **2. Providers may provide treatment without consent in accordance with a court order or in accordance with other provisions of law that authorize such treatment including the Health Care Decisions Act (§ 54.1-2981 et seq.). The provisions of these regulations are not intended to be exclusive of other provisions of law but are cumulative (e.g., see § 54.1-2970 of the Code of Virginia).** Clarification requested: When an individual has been stabilized on medications during an emergency and consent has not yet been obtained from any source can the medication be continued when discontinuing the medications would precipitate another emergency?	"Emergency" means a situation that requires a person to take immediate action to avoid harm, injury, or death to an individual receiving services or to others, or to avoid substantial property damage. The determination of the existence of an "emergency" is a clinical decision. When the standard for "emergency" is met then treatment can be provided without consent. If the standard is no longer met then you cannot provide any treatment without consent. Providers should always pursue substitute a decision-maker as soon as possible if an emergency situation occurs. This might be a legally authorized representative if the individual as been determined to lack the capacity to give consent or judicial authorization for treatment.

Participation in decision making. **12 VAC 35-115-70.**	**Section of the regulation in question:** **12 VAC 35-115-70. Participation in decision making.** **7. If the capacity of an individual to give consent is in doubt, the provider shall make sure that a professional qualified by expertise, training, education, or credentials and not directly involved with the individual conducts an evaluation and makes a determination of the individual's capacity.** **8. If the individual or his family objects to the results of the qualified professional's determination, the provider shall immediately inform the human rights advocate.** **a. If the individual or family member wishes to obtain an independent evaluation of the individual's capacity, he may do so at his own expense and within reasonable timeframes consistent with his circumstances. The provider shall take no action for which consent is required, except in an emergency, pending the results of the independent evaluation. The provider shall take no steps to designate a legally authorized representative until the independent evaluation is complete.** **b. If the independent evaluation is consistent with the provider's evaluation, the evaluation is binding, and the provider shall implement it accordingly.** **c. If the independent evaluation is not consistent with the provider's evaluation, the matter shall be referred to the LHRC for review and decision under Part IV (12 VAC 35-115-150 et seq.) of this chapter.** Clarification requested: If an individual obtains an independent evaluation as in 8 a, what are the qualifications of the evaluator? Do the same standards apply as in **# 7 "… a professional qualified by expertise, training, education, or credentials."?** If an independent evaluation is obtained how is the record created and made a part of the individual's service record?	Even though #8 does not specify qualifications, the assumption would be that individual conducting any capacity evaluation would be as indicated in #7 **"…professional qualified by expertise, training, education, or credentials…"** If the qualifications of an individual conducting an evaluation becomes an issue, "sound therapeutic practice" would prevail. The independent evaluation should be included in the service record. The following section of the regulations indicates that the individual receiving services can provide corrections or a statement to the record. **12 VAC 35-115-90. Access to and correction of services records.** **6. If an individual asks to challenge, correct, or explain any information contained in his services record, the provider shall investigate and file in the services record a written report concerning the individual's request.** **a. If the report finds that the services record is incomplete, inaccurate, not pertinent, not timely, or not necessary, the provider shall:** **(1) Either mark that part of the services record clearly to say so, or else remove that part of the services record and file it separately with an appropriate cross reference to indicate that the information was removed.** **(2) Not disclose the original services record without separate specific consent or legal authority (e.g., if compelled by subpoena or other court order).** **(3) Promptly notify in writing all persons who have received the incorrect information that the services record has been corrected and request that recipients acknowledge the correction.** **b. If the report does not result in action satisfactory to the individual, the provider shall, upon request, file in the services record the individual's statement explaining his position. If**

Participation in decision making. **12 VAC 35-115-70**	**Section of the regulation in question:** **12 VAC 35-115-70. Participation in decision making.** **7. If the capacity of an individual to give consent is in doubt, the provider shall make sure that a professional qualified by expertise, training, education, or credentials and not directly involved with the individual conducts an evaluation and makes a determination of the individual's capacity.** Clarification requested: Consumer "A" receives services from three providers who are regulated by the Human Rights Regulations. One private provider is providing residential services another private provider is providing day services and the CSB is providing case management. Which of the three providers has the responsibility for determining capacity to give consent and designating a LAR if one is determined to be needed?	Each provider has the *responsibility* to get an LAR; however, if you know a consumer is receiving services from two other licensed providers, you can attempt to work with the other providers, to the extent permitted by confidentiality requirements, to locate suitable LARs.